PERIMETER® Interbody Fusion Device
510(k) Summary
August 2013

I. COMPANY:

Medtronic Sofamor Danek USA, Inc
1800 Pyramid Place
Memphis, Tennessee 38132

II. CONTACT:

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Regulatory Affairs Specialist
Telephone: (901) 344-1272
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SEP 2 6 2013

III. PROPRIETARY TRADE NAME:

PERIMETER® Interbody Fusion Device

IV. CLASSIFICATION NAMES:

Intervertebral Fusion with Bone Graft, Lumbar

COMMON NAME:

Interbody Fusion Device

CLASS:

II

PRODUCT CODE:

MAX (21 CFR 888.3080)

V. PRODUCT DESCRIPTION:

The PERIMETER® Interbody Fusion Device consists of cages of various widths and heights which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft. The PERIMETER® Interbody Device is to be used with supplemental instrumentation.

The device is offered in Titanium Alloy (Titanium-6Aluminum-4Vanadium ELI) or PEEK Optima LT1 (Polyetheretherketone). This interbody device is offered in sterile (PEEK) or non-sterile (PEEK and Titanium Alloy) forms.

The PERIMETER® Interbody Fusion Device is offered in a variety of sizes ranging from 8mm to 20mm in height, 21mm to 28mm in length and between 19mm and 38mm in width. An array of lordosis options are provided for this device spanning from 4 degrees to 15 degrees of angulation. Both the PEEK and Titanium Alloy (Titanium-6Aluminum-4Vanadium ELI) devices are designed with teeth across both the superior and inferior surfaces to allow the implant to grip the superior and inferior end plates, thus providing

expulsion resistance. Additionally, the Titanium Alloy (Titanium-6Aluminum-4Vanadium ELI) version of this device offers lateral windows for visibility of the autogenous bone graft.

VI. INDICATIONS FOR USE:

The PERIMETER® Interbody Fusion Device is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior, lateral and oblique. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

VII. Summary of the Technological Characteristics:

The subject PERIMETER® Interbody Fusion Device has the same indications, intended use, fundamental scientific technology, design and material as the previously FDA cleared predicates; PERIMETER® Interbody Fusion Device K111525 (S.E. 08/24/2011) and K090353 (S.E. 09/29/2009). The only change in the application is a modification to the labeling.

VIII. Identification of Legally Marketed Devices:

The fundamental scientific technology, design features and indications for use for the subject PERIMETER® Interbody Fusion Device are identical to the predicate PERIMETER® Interbody Fusion Devices K111525 (S.E. 08/24/2011) and K090353 (S.E. 09/29/2009).

IX. Discussion of Non-Clinical Testing:

This modified labeling has been confirmed for the subject device by surgeons performing the procedure on cadavers. Data from this confirmatory validation supports the labeling modification. The intended use has not changed as the result of this labeling modification. Medtronic believes that the subject device is substantially equivalent to the predicate device.

X. Conclusion:

Validation and risk analysis were completed for the labeling change. Based on the validation, risk analysis and additional supporting documentation provided in this premarket notification, Medtronic believes the subject system demonstrates substantial equivalence to listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated
Ankit K. Shah
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

September 26, 2013

Re: K132700
Trade/Device Name: PERIMETER® Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 28, 2013
Received: August 29, 2013

Dear Ankit K. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Not yet assigned

Device Name: PERIMETER® Interbody Fusion Device

Indications for Use:

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Prescription Use ___X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices